WHITE PAPER ON ACCREDITATION OF BIOMEDICAL ENGINEERING PROGRAMS IN EUROPE

Version 1.3b

Draft - Discussion Paper

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IFMBE
Ad-hoc Committee on IFMBE Representation in Europe
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FOREWORD

As a reflection of major achievements towards European political as well as commercial unification, the increasing importance of the European Commission in the funding of research, and the need for quality control and harmonization in higher education, an IFMBE European working group was established in 1991, with the aim of creating a forum for the European member societies to discuss common problems and formulate responses to these. In contrast to the European societies of Medical Physics, who are organized in the European Federation of Medical Physics (EFOMP), no formal association was established by the European Biomedical Engineering Societies.

However, latest the Sorbonne declaration of May 25th, 1998 and the Bologna declaration of June 19th, 1999 made it clear, that the Biomedical Engineering societies in Europe will loose their influence on the further development of BME education, unless they are going to create a common body representing the European competence in BME towards the European Governments and the European Commission. At the same time, the important role of the national societies also became obvious as the provider of expertise to the national educational bodies, including the Universities, which, due to their autonomy, are a major factor in the development of quality control of educational programs and the mutual recognition of degrees which is a prerequisite for European agreements to work in practice, and to guarantee free movement within Europe.

The IFMBE European working group under its chairman Helmut Hutten tried to create the awareness for the need of a European body representing the national BME societies, but IFMBE as a global, international federation was not the right platform, especially since IFMBE cannot make any decisions for the European societies. At the 1st EMBEC conference in Vienna last November, IFMBE President Jean-Pierre Morucci appointed an ad-hoc committee on IFMBE representation in Europe, chaired by Niilo Saranummi, to look into the needs of the European MBE community and suggest solutions. Though any decisions must be made by the European BME societies, IFMBE intended to provide a forum for these decisions to be discussed and worked on.

The appointment of the 'Ad-hoc Committee on IFMBE Representation in Europe' was not accepted without any voices of scepticism. Some of the resentments might have been avoided by simply referring to MBE representation instead of IFMBE representation in the name of the committee, which describes its work and intentions better anyway. I myself was at first not convinced of the need for this committee and thought that the European issues would be better taken care of by the European member societies who would be able decide on the issues at hand without help from IFMBE. However, taking a hard look at the complexities and the problems to be solved, the amount of information and material to be gathered, the need for impartial decisions and the necessary resources, soon revealed that the initiation of the discussion and problem solving related to European BME representation by the IFMBE committee was a very reasonable, and, as we have seen in the meantime, successful action. Indeed, the complexity of the issues that need to be resolved is huge, and the existing knowledge about all different developments in the wide field of BME, all existing networks, structures, etc., was marginal when the committee began its work.

Instead of trying to solve all the problems of European BME representation at the same time and immediately, it is my view that we need to begin by focussing on the most important issues and create our first success stories that might bring all European biomedical engineers closer together and prepare them to deal with the problem of creating a European body that will represent all different and, to some extent, organizationally diverging areas of Biomedical Engineering and Science, a body that will correspond to and accentuate the important role of BME for the European Union.

One such focal area is higher education. And the Bologna declaration is putting much pressure on us to move fast. But it is also true that the situation is offering us a unique opportunity to achieve our goals. Politicians are actually requesting input from the experts in non-governmental organizations regarding the issues of quality of education, harmonization and accreditation. These are important issues that we ourselves are very much interested in, and that are actually solvable within the time frame set by the European educational authorities. In order to initiate widespread European cooperation on this topic, the ad-hoc committee decided to prepare a 'white paper' on BME accreditation in Europe as a discussion paper for the meeting of the European Member Societies of the IFMBE at the World Congress 2000 in Chicago. I agreed to coordinate this task. Due to the tight time schedule it had been agreed upon that the initial paper would just be a very preliminary draft, based on a paper that I had written for discussion within the ad-hoc committee. The draft shall be modified as necessary and further developed at the upcoming meetings in Chicago and Patras.

We, the authors and editors of this booklet, have done our best to provide a helpful paper on BME accreditation in Europe by putting together available material and developing possible structures and action plans. Unfortunately, a complete analysis of the European Survey on the Status of BME Accreditation was not yet available before the Chicago World Congress 2000, the deadline for this preliminary paper. My special thanks go to Zoi Kolitsi and Kalju Meigas for all the support they gave me, and to Niilo Saranummi who substantially contributed to this paper by his extensive protocols and reports of the ad-hoc committee's work.

The white paper is, in its current state, just a draft or skeleton, a working paper, far from being finished, but nevertheless, we think that it should serve its purpose, which is to provide the material for an initial discussion of representatives of all European IFMBE Member Societies on the issue of BME accreditation, for effective cooperation among these societies and also for cooperation with other interested European societies beyond the limits of IFMBE.

Joachim H. Nagel

June 2000

1. INTRODUCTION

1.1 Rationale

Traditional European structures of education, research and research funding, which are strictly national issues, are becoming more and more obsolete in a unifying and harmonizing Europe where mobility is mandatory, and need to be replaced or supplemented by structures providing the compatibility of systems.

These changes should not be limited to the countries which are currently members of the European Union, but should include all interested European countries.

Within the countries of the European Union, these changes are not just desirable, but due to the political developments, they are mandatory.

All organizations involved in the issues of education and research are therefore challenged to participate in preparing and realizing the necessary modifications of national structures as well as setting up the required new European structures and bodies.

This development includes education and research in Biomedical Engineering as well as the whole development of professions in Biomedical Engineering and related fields. Thus, all European societies representing biomedical engineering, medical physics, clinical engineering, medical informatics, artificial organs, biomaterials, etc. must address the related issues and must work together to realize the required changes in a way that is beneficial to our professions - and thus to society - and revoke negative trends such as the drifting apart of the different areas of biomedical engineering and the elimination of BME as a specific area of research funding.

Why should the European BME Societies take care of accreditation?

If they won't, others will!

Governmental authorities and university associations are ready to implement accreditation or evaluation in all disciplines, including Biomedical Engineering. If this occurs without the involvement of the BME societies, they will determine contents and quality requirements for BME programs, not the scientific societies with their inherent expertise.

Due to the European structures, this process has to be achieved on two different levels: the European and the national representation of biomedical engineering.

As a logical consequence, it appears necessary that all national and international societies with European interests in our field must work together and coordinate their activities to succeed in establishing compatible systems throughout Europe. Due to the autonomy of the universities, these should be included in the process.

To achieve these goals, a European organization is required which represents all countries and all areas of biomedical engineering and sciences.

With regard to education, the appropriate way of achieving European compatibility is to establish a European accreditation body drawing its input and guidelines from the professional societies representing the expertise and being authorized by the governmental authorities.

The process of attaining influence in the area of research funding, i.e. gaining political influence on the European Commission and the European Parliament, requires new organizational structures, major efforts and a substantial amount of time. In contrast, in order to tackle the issues of higher education, we can, as a first step providing the input requested by the educational authorities in the Bologna declaration, largely rely on the established national structures, and only need to organize European coordination and cooperation.

Thus, it appears reasonable and imperative that the European BME community should immediately address the issues of higher education: quality control, harmonization, and accreditation.

Numerous activities are currently under way to establish regional, national and even some international bodies or networks related to mobility, quality control and accreditation or evaluation of academic programs in BME. As these efforts are completely independent and uncoordinated, they are, in some cases, creating additional problems for a European harmonization. Therefore, the European BME societies should move as fast as possible and at least recommend standards regarding the most important points of a future European system. Some of these are:

- What sort of programs should be accredited: undergraduate, graduate, postgraduate, wholly biomedical engineering, partially biomedical engineering?
- Common regulations as to the degrees (Bachelor, Master, and Ph.D.), setting up minimum requirements and prerequisites for each of these degrees.
- List of topics defining BME.

As long as there is no European BME structure or association which is able and authorized to coordinate and represent the various societies, a European IFMBE subcommittee appears to be the only forum that is able to instigate and to sustain the necessary European BME initiatives, acting as an incubator for the evolving European structures.

Major players defining BME:

US: Scientific Societies - AIMBE

Europe: Universities, governmental authorities, soon perhaps governmental evaluation agencies

1.2 Goals of this White Paper on Accreditation

The first and immediate goal of this white paper on European BME accreditation is to provide the material for an initial discussion of representatives of all European IFMBE Member Societies on the issue of BME accreditation. Due to a very tight time schedule, the white paper is, in its current state, just a draft or skeleton, a working paper, far from being finished, but hopefully, it will serve its purpose for the Chicago meeting. The paper shall be modified as necessary and further developed at the upcoming meetings in Chicago and Patras.

At this initial stage of discussions on European BME accreditation, some of the chapters of this white paper remained blank as there was no material available or the ad-hoc committee had not decided on how to handle the issues. In order to serve as reminders for the upcoming discussions, the headers of the empty chapters were not removed from the paper.

2. BACKGROUND

2.1 The Bologna declaration

2.1.1 Important points of the declaration:

The Bologna declaration has been signed in 1999 by 29 European countries, among them all EU members. It underscores the importance of education and educational co-operation in the development of stable, peaceful and democratic societies. It calls for adoption of a system of easily readable and comparable degrees, in order to promote European citizens' employability, the international competitiveness of the European higher education system, and the adoption of a system essentially based on two main cycles, undergraduate and graduate. Access to the second cycle shall require successful completion of first cycle studies, lasting a minimum of three years. The degree awarded after the first cycle shall also be relevant to the European labour market as an appropriate level of qualification. The second cycle should lead to the master and/or doctorate degree.

A system of credits should be established - such as in the ECTS system - as a proper means of promoting student mobility. Credits could also be acquired in non-higher education contexts, including lifelong learning, provided they are recognised by receiving Universities concerned.

The declaration asks for the

- Promotion of European co-operation in quality assurance with a view to developing comparable criteria and methodologies, and the
- Promotion of the necessary European dimensions in higher education, particularly with regards to curricular development, inter-institutional co-operation, mobility schemes and integrated programmes of study, training and research.

In order to achieve their goals, the governmental authorities intend to pursue intergovernmental co-operation, and co-operation with non governmental European organisations with competence on higher education. They expect the universities to contribute actively to the success of their endeavour.

Progress will be assessed and new steps discussed at a meeting of the governmental authorities in 2001 in Prague.

2.1.2 Implications of the declaration

1. The Bologna declaration is not just a vague political statement, but it has to be considered as an action plan: there is a goal (to achieve a European space for higher education), there is a calendar (next meeting of ministers and higher education leaders to be held in Prague in 2001, completion of the European space within the first decade of the new millenium) and there is a programme of activities.
2. The declaration includes an invitation to institutions of higher education, i.e. the universities, to contribute to the success of the process of reform and convergence.
   Involved will be representative organisations of higher education institutions: the Association of European Universities (CRE), the Confederation of EU Rector’s Conferences and others (Eurashe and the EAIE).
   It is very important to realise that there is **no explicit invitation to scientific societies** to participate in the process! Thus, it is crucial for the scientific societies to get their act together and to tell ministers in a convincing way what kind of European system for higher education they want. This is a unique opportunity, but also a serious responsibility for the scientific societies.

3. Although the upcoming activities will be mainly intergovernmental, there is also going to be an input from the European Union: the follow up to Bologna was an important item of the agenda of recent EU ministerial meetings.

4. It is not clear up to now which body will be the authorised institution for the accreditation of programs or universities. Some governments are currently establishing such agencies, even if at this time their official purpose is the evaluation of universities as a tool of quality control. Many organisations are also trying to gain authorisation as accreditation bodies.
   Important is that the power of these agencies would be immense, if they define the standards for obtaining accreditation. This would include the content of educational courses and programmes.

5. According to the text of the declaration, a BME program may lead to a doctorate degree immediately from the bachelor degree, side-stepping the master degree. Some institutions might want to use this loophole to attract students. To avoid problems, we should make sure that this possibility will not apply to engineering programs throughout Europe. The master degree should remain a prerequisite to obtain a Ph.D. degree.

Summarising: According to most comments and interpretations of the Bologna declaration, governmental bodies and universities are thought of as the main players regarding European accreditation, in contrast to the ABET accreditation system in the U.S. However, the scientific societies have not been mentioned explicitly, and they have not been excluded, so it is completely up to them to get into the loop.

It appears very important, not to underestimate the level of change that we are going to see as a result of this initiative!

2.1.3 The necessary consequences for the European BME societies

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2.2 ABET Accreditation

(http://abet.org/abet_brochure.htm)

In the United States, accreditation is a non-governmental peer review process that ensures educational quality. Educational institutions or programs volunteer to periodically undergo this review to determine if minimum criteria are being met. Accreditation verifies that an institution or program meets the criteria. The Accreditation Board for Engineering and Technology (ABET) is responsible for the specialized accreditation of educational programs in engineering, engineering technology and engineering-related fields. Programs either receive accreditation or are denied it, but they are not ranked.
ABET is a federation of 28 professional engineering and technical societies. Representatives from these societies form the body of ABET through its Board of Directors and three working Commissions:

- Engineering Accreditation Commission (EAC)
- Technology Accreditation Commission (TAC)
- Related Accreditation Commission (RAC)

The ABET Board of Directors sets policy and approves accreditation criteria while the Commissions implement accreditation procedures and decisions. The active participation of practicing professionals allows accreditation to reflect standards set by the profession itself.

Accreditation according to ABET helps many people make important decisions about education including:

- Students choosing an educational program
- Parents seeking assurance of a quality education
- Institutions seeking to improve the education provided by their programs
- Employers recruiting well-prepared graduates
- State registration, licensure and certification boards screening applicants for entry into professional practice
- Industry seeking to voice educational needs to institutions.

ABET also evaluates engineering programs outside the United States. Programs found comparable in content and educational experience to ABET-accredited programs, but not necessarily identical in format or method of delivery, are recognized as "substantially equivalent". Substantial equivalency implies that an engineering program has prepared its graduates to enter professional practice. Substantial equivalency is not accreditation.

ABET has also entered into a number of mutual recognition agreements (MRA) with accrediting organizations in other countries. These agreements recognize other accreditation systems as comparable to ABET accreditation. In turn, these accreditation systems recommend that graduates from accredited programs in member countries be granted the same privileges for entry into the profession.

Memoranda of Understanding (MOU) are agreements through which ABET exchanges information and consults with developing accreditation organizations in other countries. This helps other countries and ABET to develop accreditation systems that will meet the engineering and educational needs of the 21st century.

Important Notes:

ABET accreditation is limited to undergraduate programs, whereas the emerging European evaluation agencies, mainly established and funded by state educational authorities, are thought as complete quality control systems including graduate, postgraduate and Ph.D. programs. Similarly, ABET, upon request by institutions outside the United States, evaluates engineering education programs leading to degrees at all levels.

Most comments on the European educational systems, including the comments on the Bologna declaration, see the multitude of different programs as the reason for the existing "chaos". In contrast, ABET identifies the diversity of educational programs in the United States as one strength of the American educational system. However, the large selection of educational offerings makes quality a vital issue. Accreditation is the quality assurance that education is meeting minimum standards.

2.3 TEMPERE

(by Zoi Kolitsi)

TEMPERE is an on-going European thematic network under the SOCRATES EU programme, involving universities and professional bodies in both fields of Medical Physics and Biomedical Engineering. As such it provides a forum for discussions and formulation of broadly accepted proposals, in the form of TEMPERE Recommendations, on issues related to a European framework for mutual co-operation and recognition in the above fields. TEMPERE has also efficiently exchanged information with professional societies, which have closely observed the TEMPERE activities. The discussion has also profited from existing valuable experience, work and results that have been produced, either individually or collectively by the professional associations.

The TEMPERE network has closely followed EU policies related to the Accreditation of Higher Education in order to focus the discussions on the relevant requirements and elaborate guidance on their fulfilment. In this process the TEMPERE network has achieved

a) to clarify and reach a common understanding on the principles concerning accreditation and quality assurance and establish a general framework within which the relevant issues can be effectively discussed
b) to establish a set of competencies that professionals should posess to meet the challenges of the professions, as these are delineated today and forcasted in the future, including a framework for their continuous updating
c) to produce a set of recommendations, concerning education, training and accreditation in the fields of Medical Physics and Medical Engineering.
d) to identify examples of widely accepted good practice and how such practice may be locally implemented.

Evidently, TEMPERE does not intend to establish standards or accreditation schemes. Nevertheless, the work accomplished within the network may provide a good starting basis for those organisations that are authorised to do so.

Presently, TEMPERE is validating its current results, before entering a next phase of expanding and detailing on the issues negotiated within the project. More information about TEMPERE may be found at http://www.inbit.gr/fine-tempere.

2.4. The American Institute of Medical and Biological Engineering (AIMBE)

(Text from the AIMBE homepage)

Statement of Purpose:

The American Institute for Medical and Biological Engineering was established with the following purposes:

1. To establish a clear and comprehensive identity for the field of medical and biological engineering
2. To promote public awareness of medical and biological engineering
3. To establish liaisons with government agencies and other professional groups
4. To improve intersociety relations and cooperation within the field of medical and biological engineering
5. To serve and promote the national interest in science, engineering, and education
6. To recognize individual and group achievements and contributions to the field of medical and biological engineering

AIMBE's principal activities include participation in the formulation of public policy; the dissemination of information, both to the public and scientific community, through publications and forums; and education.

Organization:

AIMBE's basic structure has four representative elements:

1. **The College of Fellows (COF)** - The COF is composed of distinguished individuals representing the different constituencies of the medical and biological engineering community. The initial COF is constituted with individuals selected by the membership committee. This initial membership committee consists of a group of Founding Fellows, who were considered by the steering committee to be categorically qualified for selection as fellows of AIMBE. The current membership of the COF is approximately 400, and it is expected that COF membership in a mature AIMBE will stabilize at approximately 2% of the population engaged in medical and biological engineering activities. Election to the COF will confer indefinite membership as a fellow of AIMBE, subject to the payment of dues and meeting such other conditions of good standing as provided in the bylaws.
2. **A Council of Societies (COS)** - The COS is composed from representatives of constituent professional societies. The establishment of the COS was initiated with the appointment of an Intersociety Working Group (ISWG) composed of the society representatives who attended the Pittsburgh workshop. The ISWG participated in the drafting of AIMBE bylaws, with particular focus on those issues relevant to the COS.
3. **An Industry Council (IC)** - The identification of prospective companies for membership will be initiated over the next year. An appropriate core of companies with substantial activities will be invited to proceed with the formation of the IC according to the model established for the COS.
4. **An Academic Council (AC)** - College and university programs with a substantial medical and/or biological engineering focus are eligible for membership in the AC.

Invitations for membership in the AC are extended subject to the provisions provided in the AIMBE bylaws.

Additionally, four standing commissions conduct AIMBE's principle activities. The commissions. headed by an elected vice-president, are in the areas of public policy, public awareness, education, and liaison. The roles and responsibilities of the respective commissions are elaborated in the bylaws.

AIMBE is governed by a **Board of Directors (BOD)**, which will be composed of four members elected as AIMBE officers, three members chosen by the representative councils (COS, IC, AC), one member chosen at-large from the COF, and four members elected as vice-presidents who chair AIMBE's standing commissions. An **Executive Committee (EC)** composed of the officers of AIMBE include the president, president-elect, past-president, vice-president, and secretary-treasurer. The president serves a one-year term. The president, president-elect, and past president must be fellows of AIMBE in good standing. Terms of office for the secretary-treasurer, vice-president, and at-large members of the BOD from the COF and Councils are for two years. Further elaboration of the roles and responsibilities of the BOD, EC, officers, councils, commissions, and committees and the procedures for elections and appointments are provided in the bylaws.

Mission Statement

The American Institute for Medical and Biological Engineering (AIMBE) Council of Societies was established to serve the interests of Society Members in AIMBE. These interests include:

- providing a collaborative forum for the establishment of Society Member positions on issues affecting the field of Medical and Biological Engineering
- fostering intersociety dialogue, harmony and cooperation to provide a cohesive public representation for Medical and Biological Engineering
- affecting a means for coordinating activities of Member Societies with the activites of academia, government agencies and laboratories, the health care sector, industry, the public and private biomedical communities, and AIMBE

The Council shall also represent issues of importance to Societies to the AIMBE Board of Directors.

2.5. European Federation of National Engineering Associations (FEANI)

(Text from the FEANI homepage)

FEANI was founded in 1951, to facilitate the prosperous and peaceful development of European society. Today 27 countries are represented in FEANI. The federation thus brings together more than 80 national engineering associations, all of which are recognised in their countries as the representatives of the engineering profession at the national level. Through these national associations, FEANI represents the interests of more than 1.5 million engineers in Europe.

FEANI is a founding member of the World Federation of Engineering Organisations (WFEO) and collaborates with many other organisations dealing with engineering and technology issues and engineering education.

FEANI is officially recognised by the European Commission as representing the engineering profession in Europe. The federation also has consultative status with UNESCO, UNIDO and the Council of Europe.

Objectives:

FEANI's objectives are:

to affirm the professional identity of the engineers of Europe
* by ensuring that professional qualifications of engineers of the member countries are acknowledged in Europe and worldwide
* by asserting the status, role and responsibility of engineers in society
* by safeguarding and promoting the professional interests of engineers and by facilitating their free movement within Europe and worldwide

to strive for a single voice for the engineering profession of Europe, whilst acknowledging its diversity
* in developing a working cooperation with other international organisations concerned with engineering matters
* in representing the engineers of Europe in international organisations and other decision-making bodies

Member countries:

Austria	Finland	Ireland	The Netherlands	Slovakia
Belgium	France	Italy	Poland	Spain
Cyprus	Germany	Luxembourg	Portugal	Sweden
Czech Republic	Greece	Malta	Romania	Switzerland
Denmark	Hungary	Norway	Slovenia	United Kingdom
Estonia	Iceland			

The working languages of FEANI are French, English and German.

The FEANI Register

Already at the beginning of the 1960s, FEANI was convinced that the engineering profession in Europe could not be strengthened without mutual recognition of the professional qualifications provided by the numerous and diversified national systems of education and training. Since then, FEANI has cosistently worked to set up a structure to facilitate such recognition.

The first important achievement was the establishment in 1970 of a "European Register of Higher Technical Profession".

The development of industry and the evolution of the education and training systems led to extensive revision of this Register in the beginning of the 1980s and finally, in 1987, a new FEANI Register and the Eur Ing designation were introduced. The Register was gradually developed and in 1992 the General Assembly meeting approved the principles of registration and management of the Register.

The FEANI Index

Parallel with the Register, FEANI maintains an Index, which lists the institutions of engineering higher education and their degree programmes which are recognised as fulfilling the education requirements for the Eur Ing designation. The Index also contains short descriptions of the national education systems of the members countries.

The FEANI Index is regularly updated. Schools and degree programmes are submitted for inclusion in the FEANI Index by the respective National Member, subject to approval by the General Assembly. As all FEANI National Members have approved its text, the Index is an authoritative source of information about national engineering education systems and educational institutions.

The Eur Ing designation

The Eur Ing designation is designed as a guarantee of competence for professional engineers, in order

* to facilitate the movement of practicing engineers within and outside the geographical area represented by FEANI's member countries and to establish a framework of mutual recognition of qualifications in order to enable engineers who wish to practice outside their own country to carry with them a guarantee of competence
* to provide information about the various formation systems of individual engineers for the benefit of prospective employers
* to encourage the continuous improvement of the quality of engineers by setting, monitoring and reviewing standards

The Eur Ings are listed in the FEANI Register, maintained by the Secretariat General in Brussels. Currently over 24000 European Engineers are listed in the register (beginning 1998). The "Guide to the FEANI Register" gives the details on the purpose of the Register and how it is managed.

The European Commission, in a statement to the European Parliament, has recognised the FEANI Register and the Eur Ing designation as valuable tools for the recognition of national diplomas among member states

Criteria for the Eur Ing Designation

Principles and structure of the educational and professional systems in Europe vary considerably. Their value is judged by FEANI according to the potential competence of the engineer who emerges from them.

The qualification of the engineer requires an approved engineering education following an appropriate secondary education. But full professional competence is only reached after gaining valid professional experience.

After a secondary education at a high level validated by one or more official certificates, normally awarded at about the age of 18 years, a minimum total period of seven years' formation - education, training and experience -is required by FEANI for the Eur Ing designation. This

formation consists of:

* Minimum three years of engineering education given by a university (U) or other recognised body at university level, admitted by FEANI
* Minimum two years of valid professional experience (E)
* In case the education and experience together is less than the minimum seven years' formation required, the balance to seven years should be covered by education (U), experience (E), or training (T) monitored by the approved engineering institutions, or by preliminary engineering professional experience.

In addition to these formation requirements, Eur Ing are required to comply with the FEANI Code of Conduct.

What is Engineering Education?

Any engineer listed in the FEANI Register will have a thorough knowledge of the principles of engineering, based on mathematics, physics and computer science appropriate to his or her discipline.

What is Professional Engineering Experience and Training?

The duration of professional engineering experience shall be at least two years and include the following:

* The solution of problems requiring the application of engineering science in the fields such as research, development, design, production, construction, installation, maintenance, engineering sales and marketing, and
* Management or guiding of technical staff or
* The financial, economical, statutory or legal aspects of engineering tasks, or
* Industrial and/or environmental problems.

2.6. Other networks, accreditation and certification systems

A surprisingly large number of European networks exists in the area of inter-university based academic MBE education and enabling the mobility of students. These have been funded through a number of different mechanisms of the EU Commission (Socrates, Leonardo, Tempus, Human Capital, Marie Curie). Examples of these projects include:

TEMPERE (co-ordinated by University of Patras), see www.inbit.gr/fine-tempere

EMERALD (co-ordinated by King's College of London), see www.kcl.ac.uk/erm and www.emerald2.net

MELETI (co-ordinated by University of Patras), see http://www.inbit.gr/meleti/home/index.html

BalMEP (co-ordinated by University of Linköping)

2.6.1 MELETI

(Text from the MELETI homepage)

MELETI (Medical Engineering Listed Education & Training Information) is a project under the Leonardo da Vinci Program, aiming to promote education and vocational training in Biomedical Engineering and its related subspecialties. The project's outcomes will help meet the information needs of students and professionals in this field by establishing an electronically based documentation point for information on training and educational activities.

The project will achieve its goals through the collection, validation and organization of information that will be disseminated through various routes. Different sources, such as the Internet, existing printed material and catalogues, university and training centers, libraries, industry and others will be used for data collection. The information includes directories of biomedical engineering university courses (primarily in Europe), training courses and R&D projects, inventories of books and journals, catalogues of training tools in audiovisual format and listings of web documents and sites. The project's end results will be available in printed form, on CD-ROM and on this web site. The expected impact of the project will be an increased awareness of education and training and related activities in biomedical engineering. It will also promote a wider use of existing specialized materials in this field. Information on the project will be disseminated to universities, industry, and health care organizations through newsletters, journals and presentations to national and international scientific organizations.

The project is coordinated by **the Institute of Biomedical Technology**, a non-profit organization based in Greece, with the participation of Universities and Institutions from five European countries. The end products are expected to be completed and ready for dissemination in early 2000.

The Consortium:

The Institute of Biomedical Technology
(Coordinator)

The Medical Informatics Department of the
Vrije University of Brussels, (M. Nyssen)

The National Institute for Hospital and
Medical Engineering in Budapest, (G. Bolvary)

The Bioengineering Unit of the Federico II
University of Naples, (M. Bracale)

The National School of Public Health of the
New University of Lisbon, (A. Gomes)

The Medical Physics Department of the
University of Patras, (N. Pallikarakis)

Leonardo da Vinci Program

On December 6, 1994 the European Union adopted the Leonardo da Vinci programme for the implementation of a Community vocational training policy. This program, adopted for a period of five years (1995-1999), has a key objective of supporting the development of policies and innovative action in the Member States, by promoting projects in the context of transnational partnerships which involve different organisations with an interest in training.

The program seeks to prepare for the 21st century by improving the quality of vocational training systems and their capacity for innovation which are key factors for mastering technological and industrial change and its impact upon work organisation and the competitiveness of enterprises. It is concerned with enabling vocational training to prepare for the professions of tomorrow, to anticipate change, to visualise the future, to prepare and experiment with new ways and new methods.

The program has a total budget of 620 million ECU and is open to the 15 Member States, the 3 States of the European Economic Space and more recently to Cyprus, the Czech Republic, Hungary, Romania, Poland and Slovakia. As soon as a formal decision is taken it will be also open to other Central and Eastern European Countries.

2.6.2 EMERALD

(Text from the EMERALD Web site)

EMERALD (European Medical Radiation Learning Development, supported by the EC programme Leonardo da Vinci)

The partners in the project EMERALD are a Consortium of Universities and Hospitals from the UK, Sweden, Italy and Portugal: King's College London - School of Medicine and Dentistry; University of Lund; University of Florence; King's Healthcare Trust; Lund University Hospital; Florence University Hospital; The Portuguese Oncological Institute Francisco Gentil; the International Centre for Theoretical Physics in Trieste.
Additional Partners joined the the second phase of the project EMERALD II, these being from France, Ireland, Northern Ireland, the Czech Republic and Bulgaria: Centre Alexis Vautrin at Nancy; St James's Hospital, Dublin; Northern Ireland Medical Physics Agency, Belfast; Prague Technical University; Inter-University Medical Physics Centre, Plovdiv.

The project is managed and coordinated by King's College London.

Project objectives
The last decade has seen great strides towards the emergence of professional training in Medical Physics and Medical Engineering throughout the world. The developments have, however, been patchy and of variable quality. In an attempt to support these initiatives more widely, the Leonardo EU project for European Medical Radiation Learning Development (EMERALD), a Consortium of Universities and Hospitals from the UK, Sweden, Italy and Portugal, has developed three training modules in medical radiation physics (X-ray Diagnostic Radiology, Nuclear Medicine, Radiotherapy). Each Training Module encompasses the physics and engineering of the topic and consists of a Workbook with tasks, leading to certain competencies and a CD-ROM image database (IDB). The competencies are based on the UK Institute of Physics and Engineering in Medicine (IPEM) Training scheme and on the recommendations of the European Federation of Organisations for Medical Physics (EFOMP). The training modules are for the training of young graduates and post-graduate students in medical physics or related disciplines, their tutors, as well as other Hospital employees applying radiation to medicine.

Project Deliverables
The Consortium has developed the three Training modules with a common length of 4 months (80 days) each. During this time the trainee will have to acquire the most necessary professional skills. This part of the training was called "condensed" and can be performed in all countries, where training conditions are set up. The trainee can spend a further period (typically 2 months for each module) in his/her own country where he/she can additionally study the local Regulations and professional requirements.

The project was developed in three parallel streams - one for each module:

1. Physics of X-ray Diagnostic Radiology - developed mainly by the UK partners;
2. Physics of Nuclear Medicine - developed mainly by the Swedish partners;
3. Physics of Radiotherapy - developed mainly by the Italian and Portuguese partners and Lund Univ. Hospital.

Project Phases

Project EMERALD was initiated during 1995 and has passed through the following key phases:

1. Assessment of the status and needs of Medical Radiation Physics Training
2. Development of the structure of the three common training modules
3. Development of detailed syllabi and timetables for the three training modules
4. Development of training materials - Workbooks with training tasks and Course (Teachers') Guide
5. Refereeing and Editing of the modules (internally and with external referees)
6. Practical test of the training modules (on a national and international basis)
7. Organising an European Conference on Medical Radiation Physics Training for assessment of results
8. Development of Database of digital images on CD-ROM (in 3 volumes - one for each module)
9. Development of a new enlarged project - EMERALD II

During the phase of the EMERALD II a sequence of Seminars "Train-the-Trainer" has been organised. Also an interactive Training Multimedia will be developed (Internet distributable) for the purposes of distance learning.

3. DEFINITION OF TERMS, REQUIREMENTS

3.1 IFMBE Definition of BME

Medical and Biological Engineering integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improving health and quality of life. It creates knowledge from the molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management, and methods for assessment and evaluation of technology, for the prevention, diagnosis, and treatment of disease, for health care delivery and for patient care and rehabilitation.

3.2 Accreditation, Certification, Registration, and Evaluation

Discussing the issues of accreditation requires a definition of terms. Accreditation as well as certification and registration are terms used concerning persons, academic programs, and institutions rather arbitrarily, there is no common concept for these terms. In order to avoid confusion, the white paper uses the following definitions. It should be noted, however, that some of the references are based on different definitions.

- Accreditation: Academic programs can seek accreditation from authorized bodies. To become accredited they must fulfil the requirements and pass a test.
- Certification: An accredited body can issue certificates that a product meets the requirements. E.g. an accredited MBE department (academic program) can issue certified degrees.
- Registration: To be registered with a body one needs to fulfil some base requirements and pass a registration test.
- Evaluation: Academic programs and institutions can seek evaluation from authorized bodies. They can also be evaluated at the request of educational authorities as a means of quality control.

ACCREDITATION (definition)

Accreditation is a mechanism through which a person or an organization (the accredittee) is granted by a competent body (the accreditor), by means of credentials, the needed authority to act in his/her/its capacity of commissioned officer/organization, on the particular legal qualification granted, to somebody else (the addressee).

ACCREDITATION INVOLVES EVALUATION PROCEDURES

Evaluation is the procedure conducted to verify that a program is in compliance with the appropriate accreditation criteria. It includes:

- The self-assessment questionnaire
- On site-visit
- Evaluation report

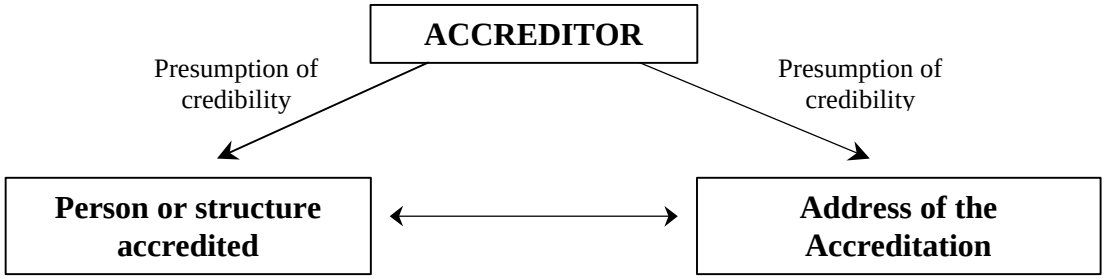
CRITERIA FOR ACCREDITATION OF EDUCATIONAL PROGRAMS

The general criteria for accreditation programs address:

- Faculty
- Curriculum
- Students
- Administration
- Facilities
- Commitment

A program is an organized educational experience that consists of a cohesive set of educational modules (topics)

ACCREDITATION / INTERESTED PARTIES



3.3 List of Topics Defining BME

3.3.1 TEMPERE

(by Zoi Kolitsi)

Biomedical Engineering

There is a long tradition of collaboration between physicians and surgeons and skilled craftsmen for the benefit of the medical practitioners and their patients With the development of Engineering as an academic and professional discipline this collaboration increased and in the latter half of the 20th century a new speciality of Biomedical Engineering developed.

Although what is included in the field of Biomedical Engineering is considered by many to be quite clear, there have been some disagreements about its definition and other terms have been used interchangeably (e.g. bioengineering). Eventually *Biomedical Engineering* prevailed as the broad umbrella term used to describe the entire field and a number of other terms were adopted to define its subspecialties. Within this context *Bioengineering* applies engineering concepts and technology to advance the understanding of biological systems. *Medical Engineering* uses engineering concepts and technology to develop instrumentation, sensors, materials, diagnostic and therapeutic devices, artificial organs and other medical devices needed in medicine. *Clinical Engineering* uses engineering, management and technology concepts to improve health care delivery systems in hospitals. *Rehabilitation Engineering* applies engineering and technology concepts to improve the quality of life for handicapped people

having chronic disabilities, by providing devices to supplement or replace physiological functions.

Clinical Engineering

Overall biomedical technology management in health care institutions is the primary application of clinical engineering. The latter has been defined as an accountable, systematic approach to ensuring that cost-effective, efficacious, safe and appropriate equipment is available to meet the demands of quality in patient care. In many hospitals the importance of technology management is already well recognised and routinely accepted. Modern health care institutions are increasingly coming to the view that technology is an integral part of all major policy and planning decisions. In many of these hospitals, technology management has become the responsibility of the Clinical Engineering department.

The development and implementation of a comprehensive technology management program requires a systematic approach. Such programs must embrace not only the technical aspects of maintaining medical equipment, but also the development of policies concerning equipment acquisition, acceptance, training, use, replacement and disposition. In essence, the primary goal of any technology management program is to ensure that the most cost-effective methods for the safe and effective operation of medical equipment are utilised. *(J. Bronzino - Management of Medical Technology)*

Teaching, Research and Development in Biomedical Engineering

There was an expansion in Biomedical Engineering during the 1950's in part produced by clinical advances e.g. the first successful case of open heart surgery and in part by the direct application of engineering e.g. the Charnley low friction replacement hip joint. Some of this and subsequent research had an educational spin-off in that it was conducted by postgraduate research students who were engineers but it became apparent that the engineering knowledge and skills needed to be supplemented by additional material e.g. the biological basis of biomedical engineering. This led to the development of instructional courses within universities predominantly in the UK and USA. These courses were at the (post-) graduate level and were either stand alone MSc or components of PhD degrees. With the growing maturity of Biomedical Engineering, an increasing number of undergraduate courses (such as Electrical, Mechanical and Electronics Engineering) contained biomedical components.

In addition to the knowledge and skills enhanced by either undergraduate or postgraduate education, the practising Biomedical Engineer commonly undertakes training to further enhance his professional, transferable and personal skills.

Today, over 200 colleges and universities in the US, Europe and other parts of the world offer education programs in Biomedical Engineering at all levels, B.Sc., M.Sc. and Ph.D. Within these programs, areas of specialisation are offered to allow students to concentrate on developing specialised skills. Such areas include bio-instrumentation, biomedical materials, Clinical Engineering, rehabilitation Engineering.

Bioengineering activity remains at an extremely high level and there is considerable research within universities, industry and health care deliverers. A considerable part of this research is carried out collaboratively.

There is a considerable overlap of Medical Physics in biomedical engineering research and development. The area of ionising radiation is unique to medical physics and Clinical and Rehabilitation Engineering falls within the ambit of biomedical engineering. Current areas of research within Biomedical Engineering instructional programs include instrumentation and medical devices, bio-materials, bio-mechanics signal processing including medical imaging, technology assessment and rehabilitation engineering.

Industry

In addition to operating and overseeing the proper use of technical equipment within a hospital, biomedical engineers play a significant role in industrial and governmental research and development. They are responsible for the development of equipment and instruments for medical applications and for personalised adaptations of devices and equipment for the disabled. In the laboratory, the biomedical engineer may play the role of expert in the biomedical aspects, the legal requirements or the clinical evaluation of a device.

A further responsibility may include the assessment of new products in relation to the regulations and market demands. Often the biomedical engineer may also have the responsibility for establishing and co-ordinating a clinical evaluation program for a new medical device. Such Engineering responsibilities have been rapidly increasing in importance, mainly at the level of the user interface requirements.

Other Areas

New application areas in several fields are emerging areas such as Cellular and Molecular Engineering and Biotechnology and are currently growing rapidly.

List of topics

Non-ionising Radiation
MRI
Ultrasound
Lasers
UV and optics
RF and microwaves
Health Protection and Safety
Physiological Measurements
Biomedical Signal Processing and Analysis
Medical Imaging
Modelling of Physiological Systems
Biomedical Instrumentation
Medical Informatics
Healthcare Telematics

Rehabilitation Engineering
Biomechanics
Biomaterials
Clinical Engineering
Cellular and Molecular Engineering

3.3.2 TEMPERE list of topics for Medical Physics

List of topics

Non-ionising Radiation
MRI
Ultrasound
Lasers
UV and optics
RF and microwaves
Health Protection and Safety
Physiological Measurements
Biomedical Signal Processing and Analysis
Medical Imaging
Modelling of Physiological Systems
Biomedical Instrumentation
Medical Informatics
Healthcare Telematics

Ionising Radiation
Radiotherapy
Nuclear Medicine
Diagnostic Radiology
Radiation Protection

Except for the last 5 topics, this is exactly the same list as for Biomedical Engineering.

For Discussion:

DEFINITION AND RANGE OF BIOMEDICAL ENGINEERING

1) There is no single valid or commonly accepted definition of BME and the range of topical areas belonging to Biomedical Engineering.
2) The numerous definitions of BME that currently exist, and the accepted range of BME, largely depend on the viewpoint and the specific interest of groups trying to protect their spheres of interest.
3) There are no reasonable system and no generally accepted criteria to decide whether a certain engineering, scientific, technical, biological or medical activity or field belongs to BME.
4) Traditional areas of BME are being claimed by other groups, like e.g. MP. Does that bring us closer together, or is there a competition about territory?
5) Do we need, and can we establish and sustain an umbrella which reasonably represents all areas of BME, MP, Bioinformatics, etc. etc. Can IFMBE serve as the clamp keeping the diverging areas together and integrate overlapping fields?

3.3.3. CRC Handbook of Biomedical Engineering (Ed. J. Bronzino).

THE DISCIPLINE OF BIOMEDICAL ENGINEERING

Biologic Effects of Electromagnetic Fields

Study of the effects of electromagnetic fields on biological tissue

Biomaterials

Design and development of bioimplantable materials

Biomechanics

Study of static and fluid mechanics associated with physiologic systems

Biomedical Instrumentation

To monitor and measure physiologic events; involves development of biosensors

Biosensors

Detection of biologic events and their conversion to electrical systems

Biotechnology

To create or modify biologic material for beneficial ends, including tissue engineering

Clinical Engineering

Design and development of clinically related facilities, devices, systems and procedures

Medical and Biologic Analysis

To detect, classify, and analyze bioelectric signals

Medical Imaging

To provide graphic displays of anatomic detail and physiologic function

Medical Informatics

Of patient-related data, interpret results and assist in clinical decision making, including expert systems and neural networks

Physiologic Modeling, Simulation, and Control

Use of computer simulations to develop an understanding of physiologic relationships

Prosthetic Devices and Artificial Organs

Design and development of devices for replacement or augmentation of bodily function

Rehabilitation Engineering

Design and development of therapeutic and rehabilitation devices and procedures

Transport Phenomena

To monitor, measure, and model biochemical processes

3.3.4 Other BME topics

- Biocomplexity,
- Bioinformatics,
- Biomaterials,
- Bionanotechnology,
- Biophotonics,
- Biosystems on nanoscale,
- Tissue engineering
- BIO-IT
  In-vitro use of biological sensors/tissue
  In-vivo use of computer technology (bionics)
  Proteins for molecular computing
  Interfacing Molecular Computing
  Strategies for co-design of integrated systems
  Methods for self-repair and self-production

3.4 Minimum requirements for BME programs

- that the student undertaking this course will have a basic university education in an appropriate engineering or physical sciences subject. The student should have received at least 3 years education in an appropriate discipline, e.g. engineering or physics, before the commencement of their education in biomedical engineering.

- the total course duration should be at least 1600 hr comprising instructional classes, a research project and private study by the student. It is expected that the student contact time would be at least 400 hr.

- the taught syllabus should cover the following four areas with approximate weightings as given:
- Basic Knowledge & Skills (basic medical & physical sciences in medicine, transferable skills, research methods) – 28-30%
- Conversion courses (0-2 taken from Mechanics and materials, Electronics, Digital signal processing) – 0-7%
- Basic Biomedical Engineering Topics – 46-50%
- Advanced Biomedical Engineering Topics – 19-20%

- appropriate methods of assessment and quality management of the educational process must be used. This must include independent and transparent quality control of the teaching and assessment procedures.

- additional educational schemes that are intended to provide the knowledge, transferable skills and research training suitable for trainee biomedical engineers should be approved by a competent authority, such as the national professional association.

- a competent authority would accredit appropriate courses provided by a university, recognising that the method of teaching and examination is the responsibility of the university.

- Some students may not require such conversion courses and the percentage breakdown recognises the variability, which is produced by whether the students require conversion classes or not.

- education needs not be undertaken in a single institution or single country, but carried out within a consortium in order to provide the range of expertise required.

4. EUROPEAN SURVEY ON THE STATUS OF BME ACCCREDITATION

4.1. Data received from returned Questionnaires

(not yet ready for publication)

4.2. Analysis of Data

(not yet ready for publication)

5. STRUCTURES OF BME ACCREDITATION

5.1 Input to educational authorities according to the Bologna declaration

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5.1 Existing structures for BME accreditation

The major players in the international arena of BME accreditation are ABET, and limited to Europe and in a different capacity, TEMPERE.

Though it is important to know these different structures and competitors for accreditation, they will probably not be able to play an important role in the European future of accreditation except for serving as models that might be partially adopted. In order to see the European future regarding our profession, we have no existing structure that we could just update or modify to fit into the changing European reality. Rather we have to look at other disciplines and try to integrate ourselves into these structures.

On a national level, evaluation agencies for academic programs have become very popular among politicians, and we are currently experiencing the creation of government funded evaluations agencies operating in individual countries or states. The members of these agencies are University and government representatives. There are no provisions to have Biomedical Engineering represented.
Also, the large national associations of engineering and electrical engineering are in the process of founding accreditation agencies, some have already done so. Here, FEANI might come into play on the European level. A European Biomedical Engineering Association would need to represent BME interests on that level.

5.3. Harmonization of European BME accreditation

Existing European situation
The current European situation is characterized by the existing organization according to ISO 9000, while at the horizon we have the competing and/or supplementary organization of quality assurance and European harmonization of university programs (see Bologna declaration).

Fig.1 shows on the left side the ISO 9000 structure. On the European level there is the European commission responsible for questions of quality (EAL, EAC). On the national level we have the accreditation council. The accreditation council recruits or nominates and accredits the accreditation agency/authority/institution. The accreditation agency selects and examines the certification agency, which is actually responsible for certification of persons and institutions. Both accreditation agency and certification agency are internally organized in so-called sector committees, which are responsible for the individual disciplines or professions.

As an independent structure, most countries have their own national accreditation council (on the right side of the graph as "various national structures") which determines the national accreditation agencies for the various disciplines. These agencies are responsible for the accreditation of academic programs. It is on this side where the "commission" of national

ministries for education and research come into play, and where the Bologna declaration has requested input from non-governmental organizations.

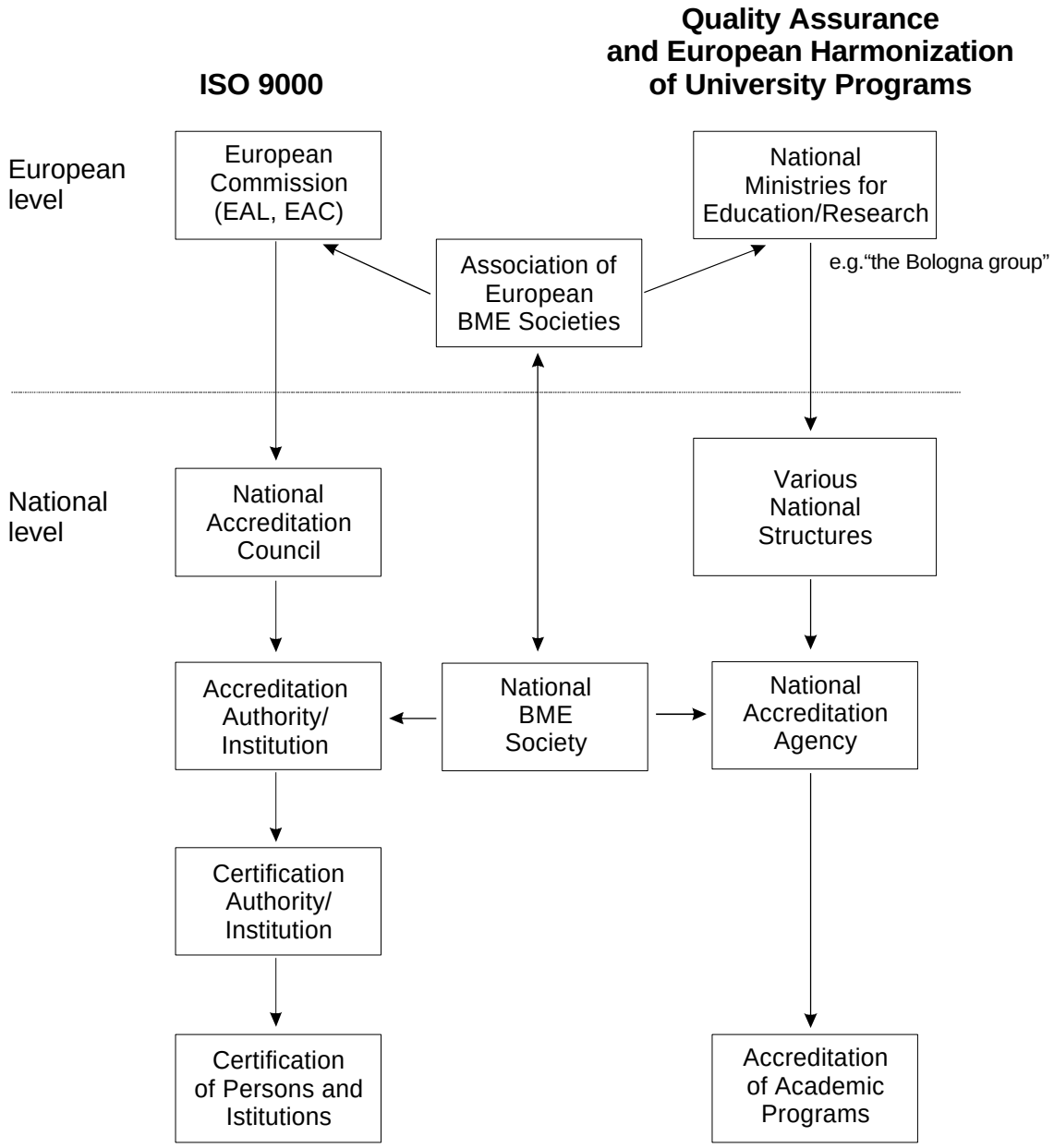

Fig. 1

As the ISO 9000 structure is increasingly considered less important or even obsolete for the future, it is the structure for quality assurance and European harmonization of university programs that will be developed politically to take over all or at least the main responsibility for questions of education, accreditation and certification.

Looking at the given structures, which at this time do not have any representation of BME, at least on the European level, it becomes apparent where and how a European Federation of BME Societies, which should be integrated somehow into IFMBE, and its national member societies will have to get into the loop. As shown in the center of the graph, the national societies have to become members of or be represented in the accreditation agencies, whereas the discussed association of European BME Societies (whatever the name and structure will be) has to provide the input to both the European Commission and the "assembly" of national ministries.

This approach appears possible, and, actually, should not be too difficult. Currently, some BME societies, are in the process of establishing representation in their responsible national accreditation or evaluation agencies and the national accreditation councils as part of an existing sector committee or even as a separate sector committee.

It appears to be obvious that with the acceptance of the BME societies in the national and international (European) bodies which are responsible for education, accreditation and certification, the doors will be wide open for further input to the European Commission regarding research funding in the field of Biomedical Engineering, which is one of the main goals of the current European activities.

Realization of an accreditation agency: EBET

Societies form board of directors, accredited by governmental educational authorities, delegating the accreditation process to authorized bodies.

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5.4. Country-specific information on existing structures for BME accreditation

5.4.1. Estonia

Chartered Engineer and Euro-Engineer in Biomedical Engineering in Estonia
(by Kalju Meigas)

The first Act of Law in Estonia recognizing the need of biomedical engineers as experts in medicine is the regulation of the Ministry of Social Affairs no. 56 from November 13, 1998. In this regulation are stated the requirements for technical experts who must participate in all radiological procedures.

The Estonian Association of Engineers (EAE) comprises all the major engineering institutions in Estonia and represents Estonian engineers in the matters of importance to the engineering profession as a whole. The declared number of engineers in EAE is 1336. EAE is a member of FEANI (European Federation of National Engineering Associations) since 1996.

At the beginning of the 1960-s, FEANI was convinced that the engineering profession in Europe could not be strengthened without mutual recognition of the professional qualification provided by the numerous and diversified national systems of education and training. In 1970 the European Register of Higher Technical Profession was established and after extensive revision in 1987 a new FEANI Register was introduced. The structure of the Register based on the two elements:

- Education. Any engineer listed in the Register will have a thorough knowledge of the principles of engineering;

- Professional engineering experience. The duration of professional engineering experience shall be at least four years and include the solution of problems requiring the application of engineering science, management or guiding of technical staff or the financial, economical, statutory or legal aspects of engineering tasks or industrial or environmental problems.

In Estonia it means that each applicant for professional accreditation as Chartered Engineer in BME is required to hold a certificate of secondary education and his total period of formation must be at least 8 years (normally more because this is not a calendar but credit year) from that point. During this period at least 4 years must have been devoted to studies in a university (Bachelor degree) acknowledged by FEANI, 2 years to gaining professional experience and the 2 intermediate years, either to complementary university courses (Master degree), or to engineering training monitored by the approved engineering institutions, or to preliminary engineering professional experience.

The FEANI Register operates at three levels:

- National Monitoring Committees in each country participating in the FEANI Register;

- European Monitoring Committee composed of eleven elected experts in the different European engineering education systems which receives the proposals from the National Monitoring Committee and checks their conformity with the rules;

- The General Assembly endorses the decisions proposed by the European Monitoring Committee and decides on borderline cases.

The Estonian National Monitoring Committee of the FEANI Register has 17 members: 7 from different member societies, 3 from enterprises, 3 from universities and other educational institutions, 2 from Ministries of Education and Economics, the President of EAE, and the representative of the FEANI Register. The Committee is elected for 4 years and confirmed by the general assembly of EAE. The main commitment of this committee is to organize ascribing of professions of Chartered Engineer and Euro-Engineer, also to organize the accreditation of different teaching courses and training activities for engineers.

The Estonian National Monitoring Committee of the FEANI Register has commissions of experts in each EAE member society. The Society for Biomedical Engineering and Medical Physics has a commission (4 members and 3 replacing members) of BME experts.

4.5.2 Other countries

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6. THE ROLE OF AND INTERACTION BETWEEN THE ORGANIZATIONS, BODIES, AUTHORITIES INVOLVED

6.1. IFMBE

6.2. The European member societies of IFMBE

6.3. European societies and organizations which are no members of IFMBE

6.4. A possible European BME Association

(EFOMP and AIMBE as models)

Mission Statement for a European BME Association

6.5. National governments

6.6. The European Commission

A European Accreditation Authority

(ABET as a model)

6.7. *Mission Statement for a European BME Accreditation Body*

6.8. Mutual Recognition of degrees

6.9. Memorandum of Understanding with ABET

7. RECOMMENDATIONS ON HOW TO ESTABLISH THE STRUCTURES FOR BME ACCREDITATION

The following question has been officially asked to the European Commission by a Member of the European Parliament on 29 October 1993:

"Does the Commission feel that the initiative of FEANI, the only one so far among the professions concerned in the general directive, may facililate the free circulation of professionals in the EEC Countries, and to what extent could the FEANI Title facilitate the recognition of national diplomas among Member States".

The question was given the following answer:

The Commission has followed the work of the FEANI (the European Federation of European Engineering Associations) and in particular, ie creation of the Eur Ing register with great interest over the years. The Commission considers that the FEANI scheme is an excellent example of self-regulation by a profession at European level and it is providing a model for other professional groups in the technical and scientific section, such as chemists and physicists.

The FEANI register recognises and builds upon the diversity of forms of engineering education which exist in the Community and can adapt to any changes which may be decided upon at national level. The procedures for dealing with applications for registration also provide a good example for national and European bodies harnessing their respective expertise.

Although the Eur Ing title cannot itself be considered as a "diploma" within the meaning of Article 1 (a) of Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher education diplomas, it may nevertheless be of assistance to the competent national authorities when they examine a request for recognition under Article 3 of the Directive. Registration on the FEANI register indicates that, whatever the duration or content of his or her initial training, the engineer has reached a certain level of professional competence, certified by his or her peers both at national and European level. Bearing in mind that Member States are required by the caseload of the Court to take into consideration when reaching their decision of recognition post-diploma professional experience, the Commission considers that an engineer who has obtained the title Eur Ing should not normally be required to undertake an adaptation period or sit an aptitude test, as provided for in Article 4 of Directive 89/48/EEC.

8. RECOMMENDATIONS ON THE FURTHER PROCEDURE TO FINALIZE THE WHITE PAPER

9. REFERENCES

10. SUPPLEMENT

10.1 The Bologna Declaration

THE EUROPEAN HIGHER EDUCATION AREA

Joint declaration of the European Ministers of Education

Convened in Bologna on the 19th of June 1999

The European process, thanks to the extraordinary achievements of the last few years, has become an increasingly concrete and relevant reality for the Union and its citizens. Enlargement prospects together with deepening relations with other European countries, provide even wider dimensions to that reality. Meanwhile, we are witnessing a growing awareness in large parts of the political and academic world and in public opinion of the need to establish a more complete and far-reaching Europe, in particular building upon and strengthening its intellectual, cultural, social and scientific and technological dimensions.

A Europe of Knowledge is now widely recognised as an irreplaceable factor for social and human growth and as an indispensable component to consolidate and enrich the European citizenship, capable of giving its citizens the necessary competences to face the challenges of the new millennium, together with an awareness of shared values and belonging to a common social and cultural space.

The importance of education and educational co-operation in the development and strengthening of stable, peaceful and democratic societies is universally acknowledged as paramount, the more so in view of the situation in South East Europe.

The Sorbonne declaration of 25th of May 1998, which was underpinned by these considerations, stressed the Universities' central role in developing European cultural dimensions. It emphasised the creation of the European area of higher education as a key way to promote citizens' mobility and employability and the Continent's overall development.

Several European countries have accepted the invitation to commit themselves to achieving the objectives set out in the declaration, by signing it or expressing their agreement in principle. The direction taken by several higher education reforms launched in the meantime in Europe has proved many Governments' determination to act.

European higher education institutions, for their part, have accepted the challenge and taken up a main role in constructing the European area of higher education, also in the wake of the fundamental principles laid down in the Bologna Magna Charta Universitatum of 1988. This is of the highest importance, given that Universities' independence and autonomy ensure that higher education and research systems continuously adapt to changing needs, society's demands and advances in scientific knowledge.

The course has been set in the right direction and with meaningful purpose. The achievement of greater compatibility and comparability of the systems of higher education nevertheless requires continual momentum in order to be fully accomplished. We need to support it through promoting concrete measures to achieve tangible forward steps. The 18th June meeting saw participation by authoritative experts and scholars from all our countries and provides us with very useful suggestions on the initiatives to be taken.

We must in particular look at the objective of increasing the international competitiveness of the European system of higher education. The vitality and efficiency of any civilisation can be measured by the appeal that its culture has for other countries. We need to ensure that the European higher education system acquires a worldwide degree of attraction equal to our extraordinary cultural and scientific traditions.

While affirming our support to the general principles laid down in the Sorbonne declaration, we engage in coordinating our policies to reach in the short term, and in any case within the first decade of the third millennium, the following objectives, which we consider to be of primary relevance in order to establish the European area of higher education and to promote the European system of higher education world-wide:

Adoption of a system of easily readable and comparable degrees, also through the implementation of the Diploma Supplement, in order to promote European citizens employability and the international competitiveness of the European higher education system.

Adoption of a system essentially based on two main cycles, undergraduate and graduate. Access to the second cycle shall require successful completion of first cycle studies, lasting a minimum of three years. The degree awarded after the first cycle shall also be relevant to the European labour market as an appropriate level of qualification. The second cycle should lead to the master and/or doctorate degree as in many European countries.

Establishment of a system of credits - such as in the ECTS system - as a proper means of promoting the most widespread student mobility. Credits could also be acquired in non-higher education contexts, including lifelong learning, provided they are recognised by receiving Universities concerned.

Promotion of mobility by overcoming obstacles to the effective exercise of free movement with particular attention to:

- for students, access to study and training opportunities and to related services

- for teachers, researchers and administrative staff, recognition and valorisation of periods spent in a European context researching, teaching and training, without prejudicing their statutory rights.

- Promotion of European co-operation in quality assurance with a view to developing comparable criteria and methodologies
- Promotion of the necessary European dimensions in higher education, particularly with regards to curricular development, inter-institutional co-operation, mobility schemes and integrated programmes of study, training and research.

We hereby undertake to attain these objectives - within the framework of our institutional competences and taking full respect of the diversity of cultures, languages, national education systems and of University autonomy - to consolidate the European area of higher education. To that end, we will pursue the ways of intergovernmental co-operation, together with those of non governmental European organisations with competence on higher education. We expect Universities again to respond promptly and positively and to contribute actively to the success of our endeavour.

Convinced that the establishment of the European area of higher education requires constant support, supervision and adaptation to the continuously evolving needs, we decide to meet again within two years in order to assess the progress achieved and the new steps to be taken.

Caspar EINEM Minister of Science and Transport (Austria)	Gerard SCHMIT Director General of French Community Ministry for Higher Education and Research (Belgium)
Jan ADE Director General Ministry of the Flemish Community Department of Education (Belgium)	Anna Mmia TOTOMANOVA Vice Minister of Education and Science (Bulgaria)
Eduard ZEMAN Minister of Education, Youth and Sport (Czech Republic)	Margrethe VESTAGER Minister of Education (Dermnark)
Tonis LUKAS Minister of Education (Estonia)	Maija RASK Minister of Education and Science (Finland)
Claude ALLEGRE Minister of National Education, Research and Technology (France)	Wolf-Michael CATENHUSEN Parliamentary State Secretary Federal Ministry of Education and Research (Germany)
Ute ERDSIEK-RAVE Minister of Education, Science, Research And Culture of the Land Scheswig-Holstein (Permanent Conference of the Ministers of Culture of the German Länders)	Gherassimos ARSENIS Minister of Public Education and Religious Affairs (Greece)
Adam KISS Deputy State Secretary for Higher Education and	Gudridur SIGURDARDOTTIR Secretary General

Science (Hungary)	Ministry of Education, Science and Culture (Iceland)
Pat DOWLING Principal Officer Ministry for Education and Science (Ireland)	Ortensio ZECCHINO Minister of University and Scientific And Technological Research (Italy)
Tatiana KOKEK State Minister of Higher Education and Science (Latvia)	Kornelijus PLATELIS Minister of Education and Science (Lithuania)
Erna HENNICOT-SCHOEPGES Minister of National Education and Vocational Training (Luxembourg)	Louis GALEA Minister of Education (Malta)
Loek HERMANS Minister of Education, Culture and Science (the Netherlands)	Jon LILLETUN Minister of Education, Research and Church Affairs (Norway)
Wilibald WINKLER Under Secretary of State of National Education (Poland)	Eduardo Marçal GRILO Minister of Education (Portugal)
Andrei MARGA Minister of National Education (Romania)	Milan FTACNIK Minister of Education (Slovak Republic)
Pavel ZGAGA State Secretary for Higher Education (Slovenia)	D.Jorge FERNANDEZ DIAZ Secretary of State of Education, Universities, Research and Development (Spain)
Agneta BLADH State Secretary for Education and Science (Sweden)	Charles KLEIBER State Secretary for Science and Research (Swiss Confederation)
Baroness Tessa BLACKSTONE of Stoke Newington Minister of State for Education and Employment (United Kingdom)	

10.2 Letter inviting organisations to participate

Toulouse, June 13, 2000

Letter inviting organisations to participate

The International Federation for Medical and Biological Engineering (IFMBE) was founded in 1959. Today IFMBE represents 47 member societies and transnational organisations with about 30.000 individual members worldwide. IFMBE together with the International Organisation for Medical Physics (IOMP) forms the International Union for Physical and Engineering Sciences in Medicine (IUPESM). In 1999 IUPESM was admitted as full member to the International Council of Sciences (ICSU). ICSU is affiliated with UNESCO and consequently with the United Nations.

The mission of IFMBE is to encourage, support, represent and unify the Medical and Biological Engineering community worldwide in order to promote health and quality of life through advancement of research, development, application and management of technology. One of its goals is the promotion of transnational collaboration in all appropriate educational, professional and ethical areas. Medical and Biological Engineering is in the midst of rapid changes with the emergence of new subdisciplines like cellular engineering, bioinformatics, nanotechnology in medicine, and telemedicine. For decades IFMBE has been the leader in Medical and Biological Engineering.

In 1999 the Bologna Declaration on Harmonisation in Higher Education was signed by 31 European governments. This declaration calls for the adoption of a system of easily readable and comparable higher education degrees in order to promote employability of European citizens and the international competitiveness of the European education system. The educational system is to be based on two main cycles: undergraduate and graduate, and the establishement of a system of credits that are recognised by the signatory states. The announced procedure for accreditation of educational courses will have major consequences for the profession of Medical and Biological Engineering as to professional qualification, collaboration between healthcare providers, industry and universities, and the establishment of international research networks.

With its longstanding commitment in educational programs, international collaboration and professional issues, IFMBE has decided to launch an initiative in the area of accreditation. Benefits from participation in these activities can be expected by all institutions involved in higher education, especially university departments. Initially, relevant data and information on educational and research activities in Medical and Biological Engineering will be collected in order to develop an action plan. A questionnaire will be sent to those institutions that can provide the necessary data and information. Next, a series of special meetings with experts will be organised in order to define the accreditation requirements considering harmonised higher education in Medical and Biological Engineering. With this action plan, IFMBE as a non-governmental organisation affiliated with ICSU also demonstrates its interest and qualification in research programmes on future technologies to benefit mankind worldwide.

With your support IFMBE can reach this challenging goal. A web-site is to be set up that shall contain relevant information and contact persons for starting the dialogue on the planned initiative. On that IFMBE website you will find the most recent information on these activities.

Jean-Pierre Morucci
President IFMBE

10.3 IFMBE EUROPEAN SURVEY ON THE STATUS OF ACCREDITATION OF HIGHER EDUCATION IN BIOMEDICAL ENGINEERING

Please, kindly fill in and return ***to Nicolas Pallikarakis*** *by* ***fax:+3061 992496*** *or* ***e-mail: nipa@bme.med.upatras.gr***

Institution:

Country	
Department	
URL	
Key areas of research	

CONTACT PERSON:

Name: First name:
Address:

Tel: Fax:
E-Mail:

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1. Does your Institution deliver a course/courses in the field of Biomedical Engineering?

   YES € NO €

   If YES, please complete:

   Course title:
   Degrees offered:
   Areas of specialisation:
   Year of establishment:

   Duration:
   Language:
   Fees:

   If NO, is the creation of such a course under consideration? YES € NO €

2. Is (Are) your course(s) delivered within the context of an inter-university national or international collaboration scheme? YES € NO €

   If YES, please list the collaborating Universities:

   -
   -
   -
   -

Is this collaboration in the context of the SOCRATES Programme?

ERASMUS YES € NO €

TEMPUS YES € NO €

Is the European Credit Transfer System (ECTS) applied? YES € NO €

3. Is your course open to foreign students? YES € NO €

If YES, are there funding schemes available to support them (eg. Socrates, Marie Curie, National grants, scholarships)? YES € NO €

Please indicate:

_____

_____

_____

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4. Are there national standards applied to the higher education in your county? YES € NO €

5. Is there a national accreditation scheme, for higher education in your country? YES € NO €

6. Is (Are) your course(s) accredited by a national accreditation body? YES € NO €

If YES, please provide details:

Accreditation body
Address:
Tel: Fax:
URL:

7. Do you have an internal Quality Assessment scheme in place? YES € NO €

8. Do you collect and analyze student opinions surveys? YES € NO €

9. Do you obtain feedback from the graduated students? YES € NO €

10. Do you review the course annually? YES € NO €

11. Is your course audited by external evaluators? YES € NO

€

12. Do you validate your program with industry and other employers? YES € NO

€

As explained in the IFMBE letter, the Federation took the initiative to address the issue of accreditation of BME courses.

Would you like to further participate in this process? YES € NO €

If YES, please complete the details for your contact person (if different from the one mentioned in the beginning of the questionnaire)

CONTACT PERSON:

Name: First name:
Address:

Tel: Fax:
E-Mail:

Please add further information or comments: